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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,612	03/20/2001	Kanji Takada	AKA-269	4679

23599 7590 03/12/2002

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/12/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/787,612

Applicant(s)

TAKADA, KANJI

Examiner

Sharmila S. Gollamudi

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1616

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

Claims 10-14 are included in this application.

Preliminary Amendment A of March 20, 2001.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 10, the phrase "suppository-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Regarding claim 11, it is unclear what is meant by the recitation of "glycyrrhizin is sufficient to overwhelm the rate of hydrolysis thereof by the intestinal flora."

The recitation of "dusting powder" in claim 13 is unclear. What is being conveyed?

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansanobu et al (JP 10226650) in view of Takada (5637319).**

Masanobu teaches an oral preparation containing glycyrrhizin and an absorption promoter. Further, the reference teaches the oral tablet having an enteric coating of carboxymethyl ethyl cellulose and the dissolution of the preparation in the large intestine. This allows the drug to be imported to the blood by remaining intact, without degradation in the upper tract of the digestive system. (Note abstract).

Masanobu does not teach the specifics of the device.

Takada teaches a controlled release preparation to deliver drugs to the gastrointestinal tract. Takada teaches an ethyl cellulose covered capsule containing a drug composition (Fig. 9). The reference teaches that the thickness of the water soluble membrane and the intestinal pressure control the release of the material so that the delivery system is site specific and delivers the drug to the large intestine (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Mansanobu's glycyrrhizin oral preparation and Takada's controlled release preparation. One would be motivated to do so since Mansanobu teaches glycyrrhizin is imported to the blood by having the drug adsorb in the large intestine and Takada teaches a colon specific drug delivery system.

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**Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3-255037 in combination of Wilson et al (Drug Delivery, Vol. 4, No. 1997, pages 201-206) in view of Sipos (4079125).**

JP 3-255037 teaches a glycyrrhizin preparation that increases the concentration of glycyrrhizin in the blood by preparing the drug with an enteric coating. This allows the drug to be absorbed by the small intestine and moved quickly to the blood. Further, glycyrrhizin is used for the therapy of liver disease and allergies.

JP 3-255037 does not teach the ethyl cellulose as the enteric coating or dusting powder.

Wilson et al teach a Pulsincap for drug delivery to the colon. The system includes an impermeable capsule body containing a drug (pg. 201, col. 2, second paragraph). The Pulsincap utilizes the physiological conditions, such as pH changes, lag-time, and degradation mechanism of intestinal bacteria, of the gastrointestinal tract to provide colon-targeted drug release (pg. 201, col.2, third paragraph and pg. 204, col. 2, second paragraph). The reference provides an example where the capsule body is coated with ethyl cellulose (pg. 202, col. 2, first paragraph). Wilson et al teach colon-specific drug delivery has advantages such as the long time contact permits the extended delivery of the drug. Further, the delayed delivery help manage plasma concentration-time while the patient sleeps (pg. 201, col. 1 to col. 2).

Sipos teaches an enteric coating for the delivery of drugs to the intestinal region. In the enteric coat method, Sipos teaches dusting talc on the tablet to prevent

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aggregation of the tablet (col. 8, line 65 to col. 9, line 4). Further, Sipos teaches enteric coating methods are well known in the art (col. 9, lines 1-4).


It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the JP reference and Wilson et al. One would be motivated to do so since JP teaches that glycyrrhizin is rapidly moved to the blood if it is adsorbed by the intestine and Wilson et al teaches the advantages of colon drug delivery as cited above. Further, one would be motivated to dust the oral preparation with talc to prevent aggregation of the tablet during the coating method as taught by Sipos.

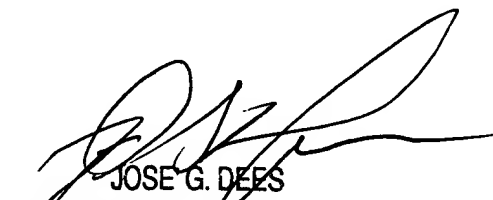
### Correspondence

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

  
SSG  
March 6, 2002

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
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